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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office
HFL-35

60 8th Street, N.E. D1244B
Atlanta, Georgia 30309

March 6, 1997

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Sylvia Lowe
Office Manager
Thomas N. Kias, MD., PC.
1010 Prince Avenue
Suite 115
Athens, Georgia 30606

WARNING LETTER

Dear Ms. Lowe:

Your facility was inspected on February 27, 1997 by a representative of the Food and Drug Administration. This inspection revealed that your facility failed to comply with certain parts of the Quality Standards for Mammography as specified in Title 21, Code of Federal Regulations, Part 900.12 as follows:

The radiologic technologist [redacted] was neither state licensed nor board certified.

The specific deficiency noted above appeared under the Level 1 heading on your MQSA Facility Inspection Report, which was issued at the close of the inspection. This deficiency may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

In addition, your response should address the Level 2 noncompliances that were listed on the inspection report provided to you at the close of the inspection. These levels 2 noncompliances are:

- Phantom image test results were not recorded for 5 of the past 12 months.

▸ Radiologic Technologist did not meet the requirement of having specific training in mammography.

It is your responsibility to ensure adherence to each requirement of the Mammograhpy Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the causes of the deficiencies that the inspection identifies and promptly initiate permanent corrective actions.

If you fail to promptly correct these deficiencies, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

* impose civil money penalties on a facility of up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standard;

* suspend or revoke a facility's FDA certificate for failure to comply with the Standards; and

* seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Within 15 working days after receiving this letter, you should notify FDA in writing of:

* the specific steps you have taken to correct all of the violations noted in this letter;

* each step your facility is taking to prevent the recurrence of similar violations;

* equipment settings (including technique factors), raw test data and calculated final results, where appropriate; and

* sample records that demonstrate proper recordkeeping procedures, if the noncompliances that were found relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

If your facility is unable to complete the corrective action within 15 working days, you should state the reason for the delay and the time within which the corrections will be completed.

Please send the original copy of your response to:

Food and Drug Administration
Compliance Branch
60 Eighth Street, NE.
Atlanta, Georgia 30309

If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call Stephanie Harrell at (404) 347-4001 ext. 5331.

Sincerely yours,

Roger E Klein

for Ballard H. Graham, Director
Atlanta District